Supreme Court, U.S.
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No. _____

In The

Supreme Court of the United States

October Term, 1995

Eugene Duvall; Patricia Sue Duvall,

Petitioners,

v.

Bristol-Myers Squibb, a Delaware Corporation; Medical Engineering Corporation, a/k/a Surgitek/Medical Engineering Corporation,

Respondents.

On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Fourth Circuit

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QUESTION PRESENTED

Do the Medical Device Amendments to the Food, Drug & Cosmetic Act preempt state law products liability claims, an issue on which the courts of appeal are in conflict?

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Eugene and Patricia Duvall respectfully petition for a writ of certiorari to review the judgment of the United States Court of Appeals for the Fourth Circuit in this case.

OPINIONS BELOW

The opinion of the Court of Appeals for the Fourth Circuit, App. at 1-20, is reported at 65 F.3d 392. The opinion of the District Court for the District of Maryland, App. at 21-24, was not officially reported; it is available on Westlaw at 1994 WL 591534.

JURISDICTION

The judgment of the Court of Appeals was entered on September 25, 1995. This Court has jurisdiction under 28 U.S.C. § 1254(1).

CONSTITUTIONAL PROVISIONS, STATUTES AND REGULATIONS INVOLVED

Article VI of the U.S. Constitution provides in pertinent part:

> This Constitution, and the Laws of the United States . . . shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.

21 U.S.C. § 360k provides:

(a) General rule

Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement –

(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and

(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

(b) Exempt requirements

Upon application of a State or a political subdivision thereof, the Secretary may, by regulation promulgated after notice and opportunity for an oral hearing, exempt from subsection (a) of this section, under such conditions as may be prescribed in such regulation, a requirement of such State or political subdivision applicable to a device intended for human use if –

(1) the requirement is more stringent than a requirement under this chapter which would be applicable to the device if an exemption were not in effect under this subsection; or

(2) the requirement –

(A) is required by compelling local conditions, and

(B) compliance with the requirement would not cause the device to be in

violation of any applicable requirement under this chapter.

21 U.S.C. § 360h(d) provides:

> **Effect on other liability.** Compliance with an order under this section shall not relieve any person of liability under Federal or State law. In awarding damages for economic loss in an action brought for the enforcement of any such liability, the value to the plaintiff in such action of any remedy provided him under such order shall be taken into account.

21 C.F.R. § 808.1(d) provides in pertinent part:

> State or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific Food and Drug Administration requirements. There are other State or local requirements that affect devices that are not preempted by section 521(a) of the act because they are not "requirements applicable to a device" within the meaning of section 521(a) of the act. The following are examples of State or local requirements that are not regarded as preempted by section 521 of the act:
>
> (1) Section 521(a) does not preempt State or local requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices (e.g., requirements such as general electrical

codes, and the Uniform Commercial Code (warranty of fitness)), or to unfair trade practices in which the requirements are not limited to devices.

STATEMENT OF THE CASE

The Duvalls brought state products liability claims against Bristol-Myers Squibb and its subsidiary Medical Engineering Corporation (collectively "Bristol-Myers"), seeking damages for the injuries caused by Bristol-Myers' Surgitek Uni-Flate 1000 penile implant. The district court granted summary judgment in favor of Bristol-Myers, concluding that the Medical Device Amendments to the Food, Drug and Cosmetic Act preempted all claims for damages under state law. The Court of Appeals for the Fourth Circuit largely affirmed, holding that the Amendments preempted all of the Duvalls' product liability claims except for breach of express warranty.

A. Statement of Facts

Surgeons implanted Bristol-Myers' prosthesis in Mr. Duvall in March 1990. Almost immediately, the device proved defective. The device was surgically removed in December 1992.

The Uni-Flate 1000 is subject to the Medical Device Amendments of 1976 ("Amendments"). Under the Amendments, the FDA classifies all medical devices into three groups. 21 U.S.C. § 360c(a). Class I devices pose little or no threat to health and therefore are subject only to "general controls." *Id.* § 360c(a)(1)(A). Class II devices

pose somewhat greater risks to health and thus are subject to "special controls." *Id.* § 360c(a)(1)(B). Class III devices present potentially unreasonable risks of illness or injury and therefore are required to undergo a thorough premarket approval process. *Id.* §§ 360c(a)(1)(C), 360e.

The FDA placed penile implants into Class III in 1983. 48 Fed. Reg. 53012, 53024 (Nov. 23, 1983). Similar devices had been introduced into the market, however, prior to the May 28, 1976, effective date of the Amendments. Bristol-Myers therefore submitted a section 510(k) "premarket notification" on the grounds that its device was "substantially equivalent" to such devices. The 510(k) notification constitutes an exemption from the class III "premarket approval" regulatory process that would otherwise have applied to the implant. 21 U.S.C. § 360c(f)(1). The FDA's grant of a 510(k) exemption, however, "does not in any way denote official approval of the device." 21 C.F.R. § 807.97.

B. Procedural History

In April 1993, the Duvalls filed suit against Bristol-Myers in Maryland state court, claiming strict liability for defective design, defective manufacture, and failure to warn; negligence in design, manufacture, marketing, testing, promotion and sale; breach of implied warranties of merchantability and fitness for a particular purpose; and breach of express warranty. They also alleged that Bristol-Myers failed to report earlier failures to the FDA, failed to conduct required investigations of failures and failed to maintain required performance specifications.

Bristol-Myers removed the action to federal court on the basis of diversity of citizenship. The district court granted summary judgment, holding that the Amendments preempted each of the Duvalls' claims. App. at 22-23. The court of appeals affirmed except with respect to the claim for breach of express warranty based on warranties made apart from the labelling, packaging or promotion of the product. App. at 19.

REASONS FOR GRANTING THE PETITION

The issue of the Amendments' preemptive scope has been fully played out in the lower federal courts and is now ripe for this Court's attention. The Fourth Circuit's decision is both wrong and in conflict with the Ninth Circuit's recent decision in *Kennedy v. Collagen Corp.*, which held that the same product liability claims asserted by the Duvalls are not preempted. 67 F.3d 1453, 1460 (9th Cir. 1995), *amended*, 1995 WL 694923 (Nov. 27, 1995), *petition for rehearing filed*, (Oct. 31, 1995). The Amendments expressly preempt only those state "requirement[s]" that relate to the "safety or effectiveness of the device" and that are "different from, or in addition to" a federal "requirement." 21 U.S.C. § 360k(a). The legislative history confirms that Congress never intended to regulate medical devices at the cost of depriving the injured of compensation through state products liability laws. Also, the FDA has interpreted the Amendments to preempt state requirements "only when the [FDA] has established specific counterpart regulations or there are other specific requirements applicable to a particular device," and has clarified that the Amendments do not preempt state

"requirements of general applicability." 21 C.F.R. § 808.1(d).

Over the last three years, however, the federal courts have concluded that the Amendments preempt state law damages actions to varying degrees. But these decisions are wildly inconsistent. For example, the courts are split regarding fraud claims. *Compare Ministry of Health v. Shiley, Inc.*, 858 F. Supp. 1426, 1440 (C.D. Cal. 1994) (claims of fraud and misrepresentation not preempted) *with King v. Collagen Corp.*, 983 F.2d 1130, 1136 (1st Cir.) (claims of misrepresentation and fraud preempted), *cert. denied*, 114 S. Ct. 84 (1993) *and Kemp v. Pfizer, Inc.*, 835 F. Supp. 1015 (E.D. Mich. 1993) (fraud and fraudulent concealment claims preempted). Others distinguish between different types of fraud. *Michael v. Shiley, Inc.*, 46 F.3d 1316, 1319 (3d Cir.) (fraud on FDA preempted but not fraud on medical community), *cert. denied*, 116 S. Ct. 67 (1995). Similarly, the narrow breach of warranty claim preserved below is preempted in some circuits but not in others. *Compare Michael*, 46 F.3d at 1327 (breach of express warranty not preempted) *with Martin v. Telectronics Pacing Systems, Inc.*, ___ F.3d ___, 1995 WL 684083 (6th Cir. Nov. 20, 1995) (breach of express warranty preempted) *and King*, 983 F.2d at 1135 (same). Courts that have found preemption have truly "run amok." Robert S. Adler & Richard A. Mann, *Preemption and Medical Devices: The Courts Run Amok*, 59 Mo. L. Rev. 895, 898 (1994).

Moreover, the circuits disagree regarding deference to the FDA's interpretation of the Amendments' preemptive scope. The court below refused to consider the FDA's view. App. at 12. But others have followed the FDA's interpretation. *Kennedy*, 1995 WL 694923 at *6; *Lohr v.*

Medtronic, Inc., 56 F.3d 1335, 1344-45 (11th Cir. 1995), *petition for cert. filed*, 64 USLW 3360 (Nov. 13, 1995).

In *Kennedy*, this shaky edifice collapsed. There, the Ninth Circuit held broadly that the Amendments do not preempt any state products liability claims. *Kennedy* thus stands in stark conflict with the Fourth Circuit's decision here, as well as the line of circuit decisions that hold there is some, albeit inconsistently defined, preemption of state products liability law.

Finally, the issue raised here is of profound importance. Thousands of persons are injured every year by defective medical products. The decision of the court below not only deprives those victims of meaningful compensation, it also negates the important public policy of deterrence which gives all manufacturers added incentive to make safe medical devices. This Court should resolve the split among the circuits and clarify that the Amendments do not preempt state products liability claims.

I. THE FOURTH CIRCUIT'S DECISION IRRECONCILABLY CONFLICTS WITH OTHER CIRCUITS' DECISIONS

Kennedy and *Duvall* create an obvious, irreconcilable conflict: the Ninth Circuit holds the Amendments do not preempt products liability law to any extent but here the Fourth Circuit found that almost all of the Duvalls' claims are preempted. The courts differ both in their reading of the statute and, more fundamentally, in their approach to the doctrine of preemption.

Each phrase within an express preemption provision limits the universe of state law preempted by a federal statute. *See Cipollone v. Liggett Group*, 112 S. Ct. 2608, 2618-19 (1992). Here, the Amendments expressly preempt only those state "requirement[s]" that (1) are "different from, or in addition to, any requirement applicable under this chapter to the device;" and (2) relate "to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter." 21 U.S.C. § 360k(a). The FDA has stated that section 360k preempts state or local requirements only when it "has established *specific* counterpart regulations or there are other *specific* requirements applicable to a *particular* device under the act" and that the Amendments do not preempt "State or local requirements of *general applicability* where the purpose of the requirement relates either to other products in addition to [medical] devices." 21 C.F.R. § 808.1(d) (emphasis added).

In holding that the Amendments preempt the Duvalls' state law claims for breach of implied warranties, strict liability, and negligence, the court below ruled that the section 510(k) process *exempting* Bristol-Myers from specific regulation and subjecting it instead only to the basic regulations applicable to all or large classes of medical devices constituted the requirements "applicable to the device under this chapter" necessary for preemption. App. at 14. The court could reach this conclusion only by ignoring the FDA's command that a "specific requirement applicable to a particular device" is required to trigger preemption. 21 C.F.R. § 808.1(d). The court below freed itself from this Court's mandate that courts confronted with an ambiguous statute must defer to the

interpretation of the federal agency charged with enforcing the statute by concluding that "§ 360k is not silent or ambiguous with respect to which requirements under the MDA give rise to preemption." App. at 12.

In *Kennedy*, in contrast, the Ninth Circuit properly held that the Amendments do not preempt state products liability actions. 1995 WL 694923 at *6. The court recognized that Congress has not addressed what constitutes a "requirement" under either state or federal law for purposes of section 360k and thus properly deferred to the FDA's interpretation. *Id.* at *4. The court concluded that the FDA's interpretation of section 360k "explicitly requires that state or local requirements *only* be preempted where there exist *specific* counterpart requirements or regulations applicable to a *particular* device." *Id.* at *4 (emphasis in original). Recognizing that in enacting the Amendments Congress sought to protect persons from dangerous medical devices, the court noted that "[p]remarket approval is supposed to benefit consumers, not create a rose garden, free from liability, for manufacturers." *Id.* at *6.

By refusing to listen to the FDA, the court below also avoided the agency's interpretation that the Amendments do not preempt state laws of "general applicability" that govern "other products in addition to devices." 21 C.F.R. § 808.1(d). Tort law is law of general applicability:

> [I]f a state common law requirement is not specifically directed at medical devices, but affects such devices in the same manner as it affects all other products, a claim based on that state law

> requirement is not preempted. Accordingly, generally applicable state common law, including tort law, is not preempted by § 360k(a).

Kennedy, 1995 WL 694923 at *8 (Reinhardt, J., concurring).

Other federal appellate decisions further compound this conflict. Besides the Fourth and Ninth Circuits, the vast majority of the remaining circuits have now addressed this issue. But the decisions are all over the map:

- First Circuit: *Talbott v. C.R. Bard, Inc.*, 63 F.3d 25 (1st Cir. 1995) (Amendments preempt all tort claims, even if defendant has defrauded the FDA); *Mendes v. Medtronic, Inc.*, 18 F.3d 13 (1st. Cir. 1994) (Amendments preempt claims, regarding "substantially equivalent" class III pacemaker, of negligent manufacture and distribution, failure to warn, and breach of implied warranty); *King*, 983 F.2d at 1137 & n.3 (Amendments preempt all claims; but concurrence concedes that express warranty claim is "a problem");

- Second Circuit: *Becker v. Optical Radiation Corp.*, 66 F.3d 18 (2d Cir. 1995) (Amendments preempt strict liability and negligence claims of defective design, defective manufacture, failure to warn, and failure to test);

- Third Circuit: *English v. Mentor Corp.*, 67 F.3d 477 (3d Cir. 1995) (Amendments preempt claims regarding class III penile prosthesis, of strict liability, negligence, and breach of implied warranty but not breach of express warranty); *Michael*, 46 F.3d at 1319 (Amendments preempt claims, of negligent design and manufacture, strict products liability, breach of implied warranty of merchantability, and fraud on FDA, but not breach of express

warranty and fraud on medical community); *Gile v. Optical Radiation Corp.*, 22 F.3d 540 (3d Cir.) (Amendments preempt claims, regarding class III intraocular lens, of products liability, negligence, and adulterated products), *cert. denied*, 115 S. Ct. 429 (1994);

- Fifth Circuit: *Feldt v. Mentor Corp.*, 61 F.3d 431 (5th Cir. 1995) (Amendments preempt claims, regarding "substantially equivalent" prosthesis, of failure to warn or label, but not design defect claims or implied warranty claim based on defective design); *Reeves v. Acromed Corp.*, 44 F.3d 300 (5th Cir.) (Amendments preempt claims, regarding "substantially equivalent" bone implant, of failure to warn even though device was misused and manufacturer withheld information from FDA), *cert. denied*, 115 S. Ct. 2251 (1995); *Stamps v. Collagen Corp.*, 984 F.2d 1416 (5th Cir.) (Amendments preempt claims, regarding class III skin injection, of defective design and manufacture, inadequate labelling, and negligent failure to warn), *cert. denied*, 114 S. Ct. 86 (1993);

- Sixth Circuit: *Martin v. Telectronics Pacing Systems, Inc.*, ___ F.3d ___, 1995 WL 684083 (6th Cir. Nov. 20, 1995) (Amendments preempt claims of defective design and manufacture, failure to warn, and breach of express warranty);

- Seventh Circuit: *Mitchell v. Collagen Corp.*, 67 F.3d 1268 (7th Cir. 1995) (Amendments preempt claims of strict liability, negligent design and manufacturing and failure to warn, but not breach of express warranty or mislabeling, misbranding and adulteration if product did not conform with FDA requirements);

- Eighth Circuit: *Martello v. Ciba Vision Corp.*, 42 F.3d 1167 (8th Cir. 1994) (Amendments preempt all claims), *cert. denied*, 115 S. Ct. 2614 (1995);

- Eleventh Circuit: *Lohr*, 56 F.3d at 1338-39 (Amendments preempt claims, regarding "substantially equivalent" device, of negligent manufacture and negligent failure to warn, but not negligent design and strict liability); *Duncan v. Iolab Corp.*, 12 F.3d 194 (11th Cir. 1994) (per curiam) (Amendments preempt claims, regarding intraocular lens, of negligence, strict liability, and breach of implied warranty).[1]

This kaleidoscope of inconsistent decisions certainly suggests that the explicit statutory language of § 360k(a) does not clearly preempt state tort claims. Normally, this would give rise to the rule that "a court may not substitute its own construction of a statutory provision for a reasonable interpretation" by the agency that administers the statute. *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 844 (1984). Yet the federal decisions are in conflict regarding the deference owed to the FDA's interpretation of the Amendments. In *Lohr*, the Eleventh Circuit deferred to the FDA because the statute's reference to "requirement" does not speak directly to the scope of preemption and the FDA's clarification is reasonable. 56 F.3d at 1344-45. Similarly, *Kennedy* recognized that Congress' lack of a clear explanation

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[1] In addition, a federal district court and one state court have rejected the notion that the Amendments preempt state tort law. *Mulligan v. Pfizer, Inc.*, 850 F. Supp. 633 (S.D. Ohio 1994); *Larsen v. Pacesetter Systems, Inc.*, 837 P.2d 1273 (Haw. 1992).

of "requirement" as used in the Amendments required deference to the FDA's interpretation of limited preemption. 1995 WL 694923 at *4; *accord Ginochio v. Surgikos, Inc.*, 864 F. Supp. 948, 952 (N.D. Cal. 1994) (FDA interpretation a permissible construction not contrary to congressional intent); *Oliver v. Johnson & Johnson, Inc.*, 863 F. Supp. 251, 253 (W.D. Pa. 1994) (finding FDA's interpretation a reasonable construction); *Ministry of Health*, 858 F. Supp. at 1440 (FDA's regulations "entitled to great weight" as not clearly in conflict with statute). The court below, however, found that section 360k was not ambiguous and thus refused to "consider the FDA's interpretation of the statute." App. at 12; *see also English*, 67 F.3d at 483 (no deference owed as FDA interpretation conflicts with statute); *Michael*, 46 F.3d at 1323 n.4 (statutory language preempts claim despite FDA's interpretation that laws of general applicability are not preempted).

The split among the Circuits reflected in this confused body of law has come to a stark head: there is no intelligible consensus among the federal courts, much less any way to reconcile the fundamental conflict between the Ninth Circuit's decision in *Kennedy* and the Fourth Circuit's decision below.

II. THE COURT OF APPEALS' DECISION IS ERRONEOUS

This Court has "never assumed lightly" that Congress has preempted state law because there is a "starting presumption that Congress does not intend to supplant state law." *New York State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins.*, 115 S. Ct. 1671, 1676 (1995).

The states' historic police powers are not to be superseded by federal law " 'unless that [is] the *clear and manifest* purpose of Congress.' " *Cipollone*, 112 S. Ct. at 2617 (emphasis added) (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)). Thus, congressional intent is the ultimate touchstone of preemption analysis. *Id.* And it is "difficult to believe that Congress would, without comment, remove all means of judicial recourse for those injured by illegal conduct." *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 251 (1984).

Here, the Amendments provide no federal damages action to replace state products liability law. Therefore, Bristol-Myers bears the burden of proving "that Congress has spoken clearly and made its intention to preempt unmistakable." *Bravman v. Baxter Healthcare Corp.*, 842 F. Supp. 747, 753 (S.D.N.Y. 1994).

A. The Court Misconstrued the Medical Device Amendments

1. The Statute Preempts Only State Regulatory Schemes

"Evidence of preemptive purpose is sought in the text *and structure* of the statute at issue." *CSX Transportation, Inc. v. Easterwood*, 113 S. Ct. 1732, 1737 (1993) (emphasis added).

Here, the statute reflects no clear intent to preempt state products liability actions. Jonathan S. Massey, "Preemption of Medical Device Tort Claims," *Trial*, Nov. 1995, at 26, 26. Rather, a fair reading of the statutory text and

structure requires the conclusion that Congress preempted only regulatory schemes comparable to the Medical Device Amendments but enacted by state legislatures or promulgated by state regulatory agencies:

> Except as provided in subsection (b) of this section, no *State or political subdivision* of a State may establish or continue in effect with respect to a device intended for human use any *requirement* –
>
> (1) which is different from, or in addition to, any *requirement* applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a *requirement* applicable to the device under this chapter.

21 U.S.C. § 360k(a) (emphasis added). The Amendments do not define "requirement." Clearly, however, the first reference to "requirement" concerns state law; the second and third references pertain to "requirements" that can be imposed by the FDA regulatory apparatus under the Amendments. This parallel structure indicates that Congress intended to preempt only state "requirements" comparable to the federal "requirements" – only state regulatory approval schemes like that created by the Amendments. A basic rule of statutory construction provides that Congress intended multiple uses of the *same word* in a single statute to have the *same meaning*. *Commissioner v. Keystone Consol. Indus., Inc.*, 113 S. Ct. 2006, 2011 (1993); *accord King v. St. Vincent's Hosp.*, 112 S. Ct. 570, 574 (1991) (statutes must be "read as a whole" because "the

meaning of statutory language, plain or not, depends on context").

That Congress intended to preempt FDA-like regulation by the states is supported by the fact that Congress expressly provided a means for states to seek an exemption for such regulatory requirements from the preemptive effect of section 360k(a):

> Upon application of a *State or a political subdivision* thereof, the Secretary may, by regulation . . . exempt from subsection (a) of this section . . . a requirement of such State or political subdivision applicable to a device intended for human use if –
>
> (1) the requirement is more stringent than a requirement under this chapter which would be applicable to the device if an exemption were not in effect under this subsection; or
>
> (2) the requirement –
>
> (A) is required by compelling local conditions, and
>
> (B) compliance with the requirement would not cause the device to be in violation of any applicable requirement under this chapter.

21 U.S.C. § 360k(b) (emphasis added). Section 360k(b)'s reference to a "State or a political subdivision" – the same phrase used in section 360k(a) – makes it plain that only a state executive or legislature, not state courts, could seek such an exemption for a state regulatory scheme. *Callan v. G.D. Searle & Co.*, 709 F. Supp. 662, 667 (D. Md. 1989) ("absurd" for courts to petition Secretary of HHS after every verdict in favor of a tort plaintiff).

Other portions of the Amendments confirm that Congress never intended to preempt state products liability law. Section 360h, which allows the FDA to order a manufacturer to make refunds, reimbursements and repairs, plainly contemplates that manufacturers remain subject to "liability" and "damages" under state law:

> **(d) Effect on other liability.** Compliance with an order issued under this section *shall not relieve any person from liability under* Federal or *State law.* In awarding damages for economic loss in an action brought for the enforcement of any such liability, the value to the plaintiff in such action of any remedy provided him under such order shall be taken into account.

21 U.S.C. § 360h(d) (emphasis added). One federal court has found this clause of "vast significance" in holding that the Amendments do not preempt state law. *Mulligan v. Pfizer Inc.*, 850 F. Supp. 633, 636 (S.D. Ohio 1994).

Had Congress intended to preempt state products liability claims, Congress could have easily stated so in the Amendments. "Congress' silence in this regard can be likened to the dog that did not bark." *Chisom v. Roemer*, 501 U.S. 380, 396 n.23 (1991). "[I]f Congress had such an intent, Congress would have made it explicit in the statute, or at least some of the Members would have identified or mentioned it at some point in the unusually extensive legislative history." *Id.* at 396. "If the intent of Congress were to nullify an entire body of state consumer protection law, and leave the victims without a remedy, it would have specifically said so." *Ministry of Health*, 858 F. Supp. at 1440.

Here, Congress' silence is deafening:

> A proper analysis of the language of section 360k requires an assessment of the likelihood that Congress in 1976 would take the dramatic step of enacting legislation to preempt common law tort claims without debate, objection, or controversy. . . . [I]t is *inconceivable* that as Draconian a measure as preempting common law tort claims found its way into the MDA in 1976 without one word from concerned members of Congress.

Adler & Mann, *Preemption and Medical Devices*, 59 Mo. L. Rev. at 940 (emphasis added). Thus, preemption of products liability claims "flies in the face of" congressional intent. *Kennedy*, 1995 WL 694923 at *6.

2. The Legislative History Reveals No Intent to Preempt State Products Liability Law

The applicable legislative history also establishes that Congress never intended to strip the injured of all access to judicial remedies. The Amendments were trumpeted as a victory for injured consumers: "[T]he legislation is written so that the benefit of the doubt is always given to the consumer. After all it is the consumer who pays with his health and his life for medical device malfunctions." 121 Cong. Rec. 59, 10,688 (1975) (statement of Sen. Kennedy), *quoted in Ministry of Health*, 858 F. Supp. at 1434. The FDA has stated that "there is nothing in the legislative history to indicate that Congress intended that the amendments should result in *less* protection for the public." 43 Fed. Reg. 18,663 (1978) (emphasis added).

Rather, the legislative history of section 360k – consistent with the statutory language and structure – supports the view that Congress intended the term "requirement" in section 360k to refer to state legislative and administrative "programs" governing the sale and distribution of devices, not to state tort law. The applicable House Report refers to only state programs that require a manufacturer to obtain approval from the state as well as from the FDA to market a device:

> In the absence of effective Federal regulation of medical devices, some States have established their own programs. The most comprehensive State regulation of which the Committee is aware is that of California, which in 1970 adopted the Sherman Food, Drug and Cosmetic Law. This law requires premarket approval of all new medical devices, requires compliance of device manufacturers with good manufacturing practices and authorizes inspection of establishments which manufacture devices.

H.R. Rep. No. 853, 94th Congress, 2d Sess. 45-46 (1976), *quoted in Callan*, 709 F. Supp. at 667. Congress clearly aimed the preemption provision only at state regulatory programs:

> The House Report demonstrates a clear concern with statutory programs administered by states and localities and never even hints to the inclusion of state common law.

Callan, 709 F. Supp. at 668.

The most recent legislative history also indicates no intent to preempt state products liability law. One provision of the Safe Medical Devices Act of 1990 – an amendment to the Amendments – requires that whenever a medical device "user facility" becomes aware that a medical device had caused any serious injury or death to a patient, that facility must make a "user report" of the death or injury to the Secretary of Health and Human Services. 21 U.S.C. § 360i(b). The accompanying legislative history expresses Congress' intent that patients injured by medical devices have a right to sue the manufacturer:

> The FDA is prohibited from disclosing the identity of medical device user facilities that file reports, except in very limited circumstances. The reports may not be admitted into evidence or otherwise used in any civil actions involving private parties. *However, there is no prohibition on civil litigation about the events that are the subject of the report.*

H.R. Rep. No. 808, 101st Cong., 1st Sess. 21 (1990) (emphasis added), *reprinted in* 1990 U.S.C.C.A.N. 6305, 6314. The "events that are the subject of the report," about which Congress has found "there is no prohibition on civil litigation," are injuries or deaths that user facilities believe are caused by medical devices. In short, "*[n]owhere* . . . in *any* of the legislative history does Congress state an intent to limit state tort actions." *Braveman*, 842 F. Supp. at 755 (emphasis added).

Therefore, contrary to the Fourth Circuit's hasty conclusion, it is sufficiently clear – both from the statutory language and the accompanying legislative history – that

section 360k simply does *not* preempt state products liability actions.

B. The Court Did Not Defer to the FDA's Interpretation

Even if the Amendments were not sufficiently clear, the requisite deference to the FDA still compels the conclusion that state products liability claims are not preempted. Courts must defer to reasonable agency interpretations of the statutes they are charged with administering unless "Congress has *directly* spoken to the *precise* question at issue." *Chevron*, 467 U.S. at 842 (emphasis added). Although both courts and agencies "must give effect to the unambiguously expressed intent of Congress," where a statute is either "silent or ambiguous with respect to the *specific issue*, the question for the court is whether the agency's answer is based on a permissible construction of the statute." *Id.* at 843 (emphasis added).

Here, the Fourth Circuit refused to consider the FDA's interpretation of the Amendments, concluding – without substantial analysis – "that § 360k is not silent or ambiguous with respect to which requirements under the MDA give rise to preemption." App. at 12. Given the split in the circuits on this issue and the general confusion concerning the Amendments' preemptive scope, it is hardly true that the Amendments *clearly* preempt state products liability law. Yet the court below struck out on its own. After noting that "every circuit court to have examined this question has determined that [the FDA's interpretation] is a reasonable interpretation of § 360k,"

the court asserted that "none of these courts have addressed the preliminary question . . . of whether the statutory language is silent or ambiguous with respect to the question at issue." App. at 12 n.5. Thus, the court imposed its own conclusion on the statutory language in order to avoid the FDA's view on preemption. But as the Ninth Circuit held, "Congress has not addressed" the threshold questions of what constitutes either a "State . . . requirement" or a " 'requirement' under the Amendments." *Kennedy*, 1995 WL 694923 at *4. "Therefore, we must look to the FDA's understanding of the scope of the MDA's statutory preemption provision since the FDA is the agency charged by Congress with implementing the MDA." *Id.*

The FDA interprets section 360k narrowly:

> State or local requirements are preempted *only* when the Food and Drug Administration has established *specific* counterpart regulations or there are other *specific* requirements applicable to a *particular* device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific Food and Drug Administration requirements.

21 C.F.R. § 808.1(d) (emphasis added). Furthermore, section 360k does not preempt "State or local requirements of *general applicability* where the purpose of the requirement relates . . . to other products in addition to devices." *Id.* (emphasis added).

The FDA has left no doubt as to its intended meaning: "There is no indication in the legislative history of section [360k] that Congress intended that the section

preempt State or local requirements respecting general enforcement, including available legal remedies." Advisory Opinion by Joseph P. Hile, Assoc. Comm'r for Reg. Affairs, FDA, Docket No. B3A-0140/AP (Mar. 2, 1984), *quoted in Ministry of Health*, 858 F. Supp. at 1435-36. Thus, even assuming the statute is not clear, the Fourth Circuit erred by not deferring to the FDA's reasonable interpretation of section 360k.

C. The Court Erroneously Based Preemption on the "Substantial Equivalency" Exemption

The Fourth Circuit held that the 510(k) notification is a requirement applicable to the device. App. at 14. A finding of "substantial equivalency" under section 510(k), however, imposes no such safety requirements. Class III devices that are "substantially equivalent" to devices already in the market prior to the May 28, 1976, effective date of the Amendments may be introduced without going through the Premarket Approval process. 21 U.S.C. § 360c(f). "Substantial equivalence" means only that the device "has the same intended use as the predicate device" and *either* "has the same technological characteristics as the predicate device" *or*

> (I) has different technological characteristics and . . . is as safe and effective as a legally marketed device, and (II) does not raise different questions of safety and efficacy than the predicate device.

21 U.S.C. § 360c(i)(1)(A). In short, "[t]he 510(k) process is focused on *equivalence*, not safety." *Lohr*, 56 F.3d at 1348. "Thus, while a substantial equivalence finding *can* be a

finding of safety and effectiveness, there is no way to tell whether a given substantial equivalence finding *is* a finding of safety and effectiveness." *Id.* Indeed, the FDA itself has stated that a determination of substantial equivalence "does not in any way denote official approval of the device." 21 C.F.R. § 807.97. "This regulation makes obvious sense because the FDA could hardly find a device 'as safe and effective' as a grandfathered device whose safety and effectiveness were never established by MDA procedures." *Lohr*, 56 F.3d at 1348. The FDA has recognized as much, establishing that its determination

> that a post-amendments device is 'substantially equivalent' is . . . not a determination that the device is not adulterated or misbranded and is otherwise safe and effective.

49 Fed. Reg. 36326-01 (Sept. 14, 1984), p. 15. Congress too has found that such products are essentially unregulated:

> [M]any manufacturers need not expect to meet performance standards or demonstrate safety and efficacy in a PMA; all they need do is demonstrate substantial equivalence and the barriers to begin and continue marketing are down. Once such equivalence is shown, devices are marketed in a regulatory system that treats all of them the same. They are subjected to general controls and no more.

House Subcomm. on Oversight and Investigations, Comm. on Energy and Commerce, 98th Cong., 1st Sess., *Medical Device Regulation: The FDA's Neglected Child* 34 (Comm. Print 1983).

The FDA's finding that Bristol-Myers' implant was "substantially equivalent" subjected the device only to

the "general controls." *See* Letter from Halyna P. Breslawec, Director, Division of Gastroenterology-Urology and General Use Devices, FDA, to Betty A. Lock, Director, Regulatory Affairs, Surgitek (Jan. 6, 1988), App. at 31. Nevertheless, the court below ruled that these controls impose a requirement specifically applicable to Mr. Duvall's prosthesis. App. at 14.

The court fundamentally misconstrued the nature of these "general controls." "General controls" apply to all medical devices in each of the three classes. They include requirements for annual registration, listing of devices, good manufacturing practices ("GMP's"), and generic labeling requirements, not specific design or manufacturing requirements. 21 C.F.R. § 807.20-.39. GMP's require manufacturers to establish a quality assurance program and include requirements for buildings, equipment, maintenance schedules, and record keeping. 21 C.F.R. § 820.1-.198. But GMP's do not dictate or even suggest the manufacturing method for a particular device.

Similarly, the "labeling requirements" do not control in any manner the warnings, cautions, or warranties that can be placed on the labels of particular implants. Rather, they simply require that any labelling for *any* medical device bear the name and location of the manufacturer, that "intended uses" of the device be defined, and include recommendations by the FDA on how to define "directions for use." 21 C.F.R. §§ 801.1-801.15. The FDA has promulgated some specific labeling requirements for specific devices such as IUDs and tampons. *See* 21 C.F.R. §§ 801.427-.430. But there are no such requirements applicable to this implant.

In sum, the FDA's "substantial equivalence" finding does not constitute a safety requirement or FDA approval:

> This letter immediately will allow you to begin marketing your device as described. An FDA finding of substantial equivalence of your device to a pre-amendments device . . . permits your device to proceed to market, but it does not mean that FDA *approves* your device. Therefore, you may not promote or in any way represent your device or its labeling as being *approved* by FDA.

Letter from Breslawec to Lock (emphasis in original), App. at 32. The Fourth Circuit plainly erred by holding that the 510(k) process and the "general controls" constitute a safety requirement specifically applicable to this particular device.

III. THE ISSUE IS PROFOUNDLY IMPORTANT

The availability of a remedy is important not only to the Duvalls but also to all those who are injured by dangerous medical devices each year. Such devices include more than 41,000 separate products falling into 1,700 different categories, ranging from bedpans to heart valves. Massey, "Preemption of Medical Device Tort Claims" at 26. Although the Amendments attempt to regulate the introduction of dangerous devices into the market, they do not provide any compensatory remedy to those injured by devices that make it to the market. While the court below left the Duvalls with one narrow claim for breach of express warranty, other courts have held there is absolutely no compensatory remedy available to

victims of defective medical devices. The lack of any remedy violates the "just principle that there should be a remedy for every wrong." *Hess v. Port Authority Trans-Hudson Corp.*, 115 S. Ct. 394, 407 (1994) (Stevens, J., concurring) (citing *Marbury v. Madison*, 1 Cranch 137, 163, 2 L.Ed. 60 (1803)). "[W]here there is a legal right there is also a legal remedy. . . . [E]very right, when withheld, must have a remedy, and every injury its proper redress." *Bush v. Lucas*, 462 U.S. 367, 373 n.10 (1983) (quoting 3 William Blackstone, Commentaries *23, *109).

Tort actions serve not only a compensatory but also a deterrent function. William Landes & Richard Posner, *The Economic Structure of Tort Law* 11 (1987). State products liability actions remain "a powerful incentive for improving product safety." *Bravman*, 842 F. Supp. at 761. By holding that the Amendments preempt state products liability claims, the court below nullified this function of tort law, leaving the FDA as the sole arbiter of medical device safety. But many deadly medical devices have reached the market despite the FDA's review.[2] And the

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[2] *See* House Subcomm. on Oversight and Investigation, Comm. on Energy and Commerce, 103rd Cong., 1st Sess., *Less Than the Sum of Its Parts: Reforms Needed in the Organization, Management and Resources of the Food and Drug Administration Center for Devices and Radiological Health* (Comm. Print 1993) (describing FDA regulatory failures); House Subcomm. on Oversight and Investigations, Comm. on Energy and Commerce, 98th Cong., 1st Sess., *Medical Device Regulation: The FDA's Neglected Child* 1 (Comm. Print 1983) (describing how FDA "has failed to enforce the new device law effectively and efficiently since its enactment in 1976").

FDA does not want the job: The FDA does not agree that the Amendments preempt state products liability law.

CONCLUSION

For the above reasons, the Duvalls respectfully request that this Court grant their petition for a writ of certiorari.

Respectfully submitted,

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PUBLISHED

UNITED STATES COURT OF APPEALS

FOR THE FOURTH CIRCUIT

EUGENE DUVALL; PATRICIA SUE DUVALL, *Plaintiffs-Appellants,* v. BRISTOL-MYERS-SQUIBB COMPANY, a Delaware Corporation; MEDICAL ENGINEERING CORPORATION, a/k/a Surgitek/Medical Engineering Corporation, *Defendants-Appellees.* FOOD & DRUG ADMINISTRATION, *Amicus Curiae.*	No. 94-1520.

Appeal from the United States District Court
for the District of Maryland, at Baltimore
Frederic N. Smalkin, District Judge.
(CA-93-1072-S)

Argued: Nov. 1, 1994

Decided: Sept. 25, 1995

Before WIDENER and WILKINS, Circuit Judges, and MICHAEL, United States District Judge for the Western District of Virginia, sitting by designation

Affirmed in part and reversed and remanded in part by published opinion. Judge Wilkins wrote the opinion, in which Judge Widener and Judge Michael joined.

COUNSEL

ARGUED: Gary Lester Wilson, ROBINS, KAPLAN, MILLER & CIRESI, Minneapolis, MN, for appellants. William James Murphy, Murphy & Shaffer, Baltimore, MD, for appellees. **ON BRIEF:** Bruce Finzen, ROBINS, KAPLAN, MILLER & CIRESI, Minneapolis, MN; David B. Shapiro, Baltimore, MD; Lewis J. Saul, Bethesda, MD, for appellants. Robert T. Shaffer, III, Murphy & Shaffer, Baltimore, MD; John F. Brenner, McCarter & English, Newark, NJ, for appellees.

OPINION

WILKINS, Circuit Judge:

Eugene Duvall appeals a decision of the district court granting summary judgment to Bristol-Myers Squibb Company (Bristol-Myers)[1] on the basis that Duvall's claims are preempted by 21 U.S.C.A. § 360k (West Supp.1995), enacted as a part of the Medical Device Amendments of 1976 (MDA) to the Federal Food, Drug,

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[1] Duvall filed suit against Bristol-Myers and its wholly-owned subsidiary, Medical Engineering Corporation. We refer to both as Bristol-Myers.

and Cosmetic Act.[2] We affirm the district court with respect to the majority of Duvall's claims. However, because we conclude that § 360k does not preempt Duvall's express warranty claim to the extent that it may be based on Bristol-Myers' voluntarily-made representations regarding its product, we reverse in part and remand for further proceedings.

I.

In 1990, Duvall underwent surgery to implant a penile prosthesis as treatment for erectile impotence. The prosthesis, a "Surgitek Uni-Flate 1000," was manufactured and marketed by Bristol-Myers. The device ultimately failed and was explanted two years later. Duvall filed suit against Bristol-Myers in state court, claiming breach of express warranty; breach of implied warranties of merchantability and fitness for a particular purpose; strict liability for defective design, defective manufacture, and failure to warn; and negligence in design, manufacture, marketing, testing, promotion, and sale. Bristol-Myers removed the action to federal court on the basis of diversity of citizenship.

The district court, noting its recent decision in *Griffin v. Medtronic, Inc.*, 840 F.Supp. 396 (D.Md.1994) (holding that the MDA preempted state-law claims involving a medical device marketed after premarket approval),

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[2] Patricia Duvall, Duvall's wife, also appeals the decision of the district court granting summary judgment to Bristol-Myers on her claim for loss of consortium. We address her claim separately below.

appeal docketed, No. 94-1219 (4th Cir. Feb. 23, 1994), granted Bristol-Myers' motion for summary judgment, ruling that all of Duvall's state-law claims were preempted by § 360k of the MDA. The material facts are not in dispute, and the issues before us are questions of law subject to de novo review. *Higgins v. E.I. DuPont de Nemours & Co.*, 863 F.2d 1162, 1166-67 (4th Cir.1988).

II.

Congress established a scheme for comprehensive regulation of medical devices in the Medical Device Amendments of 1976 to the Federal Food, Drug, and Cosmetic Act. *Mendes v. Medtronic, Inc.*, 18 F.3d 13, 14 (1st Cir.1994). The MDA authorizes the Food and Drug Administration (FDA) to classify medical devices intended for human use into three categories "based on the degree of regulation necessary to assure safety and effectiveness." *Id.*; *see* 21 U.S.C.A. § 360c (West Supp.1995). Class I devices, such as tongue depressors, which do not present an unreasonable risk of illness or injury, are subject only to general controls. 21 U.S.C.A. § 360c(a)(1)(A); 21 C.F.R. § 880.6230 (1994). Class II devices, such as bone-conduction hearing aids, for which "general controls by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the device," are subject to special controls. 21 U.S.C.A. § 360c(a)(1)(B); 21 C.F.R. § 874.3300 (1994). Class III devices are those devices: (1) for which there is insufficient information to determine that the controls applicable to Class I and II devices are alone enough to provide reasonable assurance of the safety and effectiveness of the device; and (2)(a) that are to be used for "supporting

or sustaining human life" or that are "of substantial importance in preventing impairment of human health" or (2)(b) that "present[ ] a potential unreasonable risk of illness or injury." 21 U.S.C.A. § 360c(a)(1)(C). This class of devices is subject to the most stringent MDA controls. *See King v. Collagen Corp.*, 983 F.2d 1130, 1131 (1st Cir.) (Torruella, J.), *cert. denied*, 114 S.Ct. 84, 126 L.Ed.2d 52 (1993). Class III devices include implantable pacemakers and replacement heart valves. 21 C.F.R. §§ 870.3610, 870.3925 (1994). Penile inflatable implants are classified as Class III medical devices. 21 C.F.R. § 876.3350 (1994).

In order to market a Class III device, a manufacturer generally must obtain premarket approval from the FDA. Premarket approval requires submission of a detailed application, including clinical data, manufacturing processes, and proposed labeling, *see* 21 U.S.C.A. § 360e(c) (West Supp.1995), and is intended "to provide reasonable assurance of [the] safety and effectiveness" of the device, 21 U.S.C.A. § 360c(a)(1)(C). In the case of a Class III device for which the FDA does not yet require premarket approval, the manufacturer may market the item after showing that it is "substantially equivalent" to a device marketed before the effective date of the MDA. *See* 21 C.F.R. § 807.100(a) (1994); *Mendes*, 18 F.3d at 14-15. To do so, 90 days before marketing a device a manufacturer must submit a premarket notification, known as a 510(k) Notification, including specified information; the FDA must then clear the device for marketing. 21 U.S.C.A. § 360(k) (West Supp.1995); 21 C.F.R. §§ 807.87, 807.90, 807.100 (1994).

Bristol-Myers' prosthesis reached the market through the substantial equivalence process. Upon completion of

clinical trials of the device under an investigational device exemption (IDE), *see* 21 U.S.C.A. § 360j(g) (West Supp.1995), Bristol-Myers submitted a 510(k) Notification that included information relating to the design and engineering of the device, clinical studies under the IDE, the similarity of the device to other penile prostheses marketed before passage of the MDA, and proposed packaging, labeling, and use instructions. At the FDA's request, Bristol-Myers supplied additional information on sterilization techniques, testing protocols, design of specific components of the device, package inserts, indicated uses, and fluid requirements. The FDA later cleared the device for marketing.

III.

Duvall argues that his state-law claims are not preempted by § 360k for two reasons. He first maintains that § 360k preempts only state-imposed requirements with respect to medical devices that are different from or additional to those of the MDA and that because common-law claims do not impose requirements, they are not preempted. Although we agree with Duvall that § 360k preempts only state-imposed requirements, we cannot agree that common-law claims are not requirements within the meaning of § 360k. Second, Duvall contends that even if § 360k preempts state requirements imposed by judicial decision, any requirements applicable to Bristol-Myers' prosthesis under the MDA do not give rise to preemption.

A.

The doctrine of preemption is based on the Supremacy Clause of the United States Constitution. U.S. Const. art. VI, cl. 2.[3] It has been clear since *M'Culloch v. Maryland*, 17 U.S. (4 Wheat.) 316 (1819), that a state law is invalid to the extent that it conflicts with federal legislation. *Cipollone v. Liggett Group, Inc.*, 112 S.Ct. 2608, 2617 (1992) (plurality). However, preemption should not be found too readily; " 'the historic police powers of the States [are] not to be superseded . . . unless that [is] the clear and manifest purpose of Congress.' " *Id.* (alteration in original) (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)).

A federal law preempts a state law in any of several situations. For example, state law is preempted when Congress expressly so provides, *see Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977); when federal regulation of a legislative field is so comprehensive that there is no room for supplementary state regulation, *see Rice*, 331 U.S. at 230; or when the state law is in actual conflict with a federal provision, *see Pacific Gas & Elec. Co. v. State Energy Resources Conservation & Dev. Comm'n*, 461 U.S. 190, 204 (1983). Because Congress included an express preemption provision in the MDA, we need address only the scope of the statutory language. *See Cipollone*, 112 S.Ct. at 2618 (inclusion of an express preemption provision implies

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[3] "This Constitution, and the Laws of the United States which shall be made in Pursuance thereof . . . shall be the supreme Law of the Land; . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const. art. VI, cl. 2.

that matters beyond the reach of the provision are not preempted).

Section 360k of the MDA provides in pertinent part:

> Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement –
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C.A. § 360k(a).[4] The language of this section expressly reveals congressional intent that the MDA preempt state-imposed requirements that are different from or additional to those applicable to the device under Chapter 9 of Title 21 and that relate either to the safety or effectiveness of the device or to other matters encompassed in requirements applicable to the device under Chapter 9 of Title 21. The question then becomes whether state-law claims may impose requirements within the meaning of § 360k. We conclude that they may.

In *Cipollone*, the Supreme Court addressed the question of whether state common-law claims against a cigarette manufacturer were preempted by § 5(b) of the

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[4] States and local governments may apply for an exemption to § 360k(a) in specified circumstances. *See* 21 U.S.C.A. § 360k(b).

Public Health Cigarette Smoking Act of 1969, which provided that "[n]o requirement or prohibition based on smoking and health shall be imposed under State law with respect to the advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provisions of this Act." *Cipollone*, 112 S.Ct. at 2617 (internal quotation marks omitted). A plurality of the Court concluded that the phrase "requirement or prohibition" necessarily included common-law claims:

> The phrase "[n]o requirement or prohibition" sweeps broadly and suggests no distinction between positive enactments and common law; to the contrary, those words easily encompass obligations that take the form of common law rules. As we noted in another context, "[state] regulation can be as effectively exerted through an award of damages as through some form of preventive relief. The obligation to pay compensation can be, indeed is designed to be, a potent method of governing conduct and controlling policy."

Id. at 2620 (alteration in original) (quoting *San Diego Bldg. Trades Council v. Garmon*, 359 U.S. 236, 247 (1959)). Moreover, the plurality noted, damages actions predicated upon state common-law duties impose requirements under state law. *Id.* at 2620-21. Thus, the plurality determined that common-law claims were requirements within the plain language of the provision and were preempted to the extent that they were within the scope of the preemption provision. *Id.* at 2621. Because of the similarity between the language of § 360k and the statute at issue in *Cipollone*, we conclude that the plain language of the MDA mandates the same conclusion with respect to

the use of the term "requirement" in that statute. *See Gile v. Optical Radiation Corp.*, 22 F.3d 540, 542 (3d Cir.) ("[T]he Supreme Court has clearly stated that the word 'requirement,' in the context of an express preemption provision, includes state law claims."), *cert. denied*, 115 S.Ct. 429 (1994).

In addition, we note that the FDA interprets the word "requirement" in § 360k to include duties imposed by state common law:

> [N]o State or political subdivision of a State may establish or continue in effect any requirement with respect to a medical device intended for human use having the force and effect of law (whether established by statute, ordinance, regulation, *or court decision*), which is different from, or in addition to, any requirement applicable to such device under any provision of the act and which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under the act.

21 C.F.R. § 808.1(b) (1994) (emphasis added). The interpretation of § 360k to include requirements "established by . . . court decision" is reasonable. Accordingly, had we not already determined that the plain language of § 360k compels the conclusion that the term "requirement" includes court decisions, we would defer to the interpretation offered by the FDA. *See Chevron U.S.A. Inc. v. Natural Resources Defense Council*, 467 U.S. 837, 842-44 (1984).

Further, other courts of appeals uniformly have concluded that state-law claims are within the preemptive

scope of § 360k. *See, e.g., National Bank of Commerce of El Dorado v. Kimberly-Clark Corp.*, 38 F.3d 988, 991-92 (8th Cir.1994); *Gile*, 22 F.3d at 542; *Mendes*, 18 F.3d at 16; *Stamps v. Collagen Corp.*, 984 F.2d 1416, 1421 (5th Cir.), *cert. denied*, 114 S.Ct. 86 (1993).

We therefore conclude that state-law claims are preempted by § 360k to the extent that, if successful, such claims would impose requirements under state law different from or in addition to requirements applicable to a device under the MDA.

B.

Duvall next argues that even if state common-law claims impose requirements within the meaning of § 360k, that provision nonetheless does not preempt his claims because there is no requirement applicable to Bristol-Myers' prosthesis under Chapter 9 of Title 21 from which a state-imposed requirement would differ. Duvall maintains that state-law claims are preempted only when the FDA has adopted specific requirements applicable to a single device or class of devices. In support of this argument, Duvall points to 21 C.F.R. § 808.1(d) (1994), which interprets the phrase "any requirement applicable . . . to the device" and which provides that:

> State or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different

> from, or in addition to, the specific Food and Drug Administration requirements.

Because the FDA has not adopted specific provisions with respect to penile prostheses, Duvall maintains, § 360k does not protect Bristol-Myers from liability under state law.

In analyzing Duvall's argument, we must first determine whether the phrase "any requirement applicable . . . to the device" in § 360k is ambiguous, thus opening the door for agency interpretation. *See Chevron*, 467 U.S. at 842-43 ("If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress."). If so, we must then consider whether the interpretation offered by the FDA is a reasonable one. *Id.* at 844.

Under *Chevron*, a court should defer to an agency's reasonable interpretation of a statute "if the statute is silent or ambiguous with respect to the specific issue." *Id.* at 843. However, we conclude that § 360k is not silent or ambiguous with respect to which requirements under the MDA give rise to preemption. The section plainly provides that *any* requirement that is applicable to the device preempts a different or additional state-imposed requirement.[5] Therefore, we do not consider the FDA's interpretation of the statute.

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[5] We note that every circuit court to have examined this question has determined that § 808.1(d) is a reasonable interpretation of § 360k. *See, e.g., Martello v. Ciba Vision Corp.*, 42 F.3d 1167, 1168 (8th Cir.1994), *cert. denied*, 115 S.Ct. 2614 (1995); *National Bank of Commerce*, 38 F.3d at 997; *Stamps*, 984 F.2d at 1424 n. 8; *cf. Mendes*, 18 F.3d at 16 (relying in part on § 808.1(d)

Bristol-Myers argues that there are two sources of requirements applicable to its prosthesis under the MDA: the good manufacturing practice (GMP) and labeling requirements, found in 21 C.F.R. pts. 801 and 820 (1994); and the 510(k) Notification.[6]

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without explicitly determining that it is a reasonable interpretation of § 360k). However, none of these courts have addressed the preliminary question required by *Chevron* of whether the statutory language is silent or ambiguous with respect to the question at issue. Because § 360k is not ambiguous, we need not consider whether § 808.1(d) is a reasonable interpretation of the statute.

[6] Bristol-Myers also contends that the regulation classifying penile inflatable implants as Class III devices, *see* 21 C.F.R. § 876.3350, is a requirement applicable to the device under the MDA. We disagree. The classification of penile inflatable implants as Class III medical devices is not a requirement applicable to the device for the simple reason that the classification regulation does not itself require Bristol-Myers to do (or not to do) anything. Rather, the regulation merely describes penile inflatable implants, states that they are in Class III, and provides that premarket approval is not yet required. *See* 21 C.F.R. § 876.3350. In short, although classification of Bristol-Myers' prosthesis as a Class III device may result in certain requirements being imposed upon it, the classification itself is not one of those requirements. *Cf. Elbert v. Howmedica, Inc.*, 841 F.Supp. 327, 331 (D.Haw.1993) (regulation classifying knee prostheses as Class II devices is not a requirement giving rise to preemption). *But see Anguiano v. E.I. DuPont De Nemours & Co.*, 44 F.3d 806, 810 (9th Cir.1995) (dicta) ("Because of the more extensive requirements imposed on Class III devices, the MDA preempts state law regarding a Class III device even if the only MDA regulation specifically addressing the device is an identification regulation."); *Cameron v. Howmedica, Div. of Pfizer Hosp. Prods. Group, Inc.*, 820 F.Supp. 317, 320-21 (E.D.Mich.1993) (regulation placing hip replacement devices in Class III is a requirement giving rise to preemption).

The GMP requirements include, *inter alia*, standards for production facilities, quality assurance, monitoring of package labels, and device failure reporting requirements. *See* 21 C.F.R. pt. 820. The labeling requirements mandate the content of labels and the prominence of required statements. *See* 21 C.F.R. pt. 801. Under the plain, unambiguous language of § 360k, these are clearly requirements applicable to Bristol-Myers' prosthesis under the MDA. They therefore give rise to preemption. *See Mendes*, 18 F.3d at 18-19. *But see Oja v. Howmedica, Inc.*, 848 F.Supp. 905, 906-07 (D.Colo.1994).

A 510(k) Notification also imposes requirements on the device. The FDA mandates that a 510(k) Notification include, *inter alia*, "[p]roposed labels, labeling, and advertisements sufficient to describe the device, its intended use, and the directions for its use"; a statement indicating the similarity of the device to currently marketed devices (including data to support the statement, such as information on similarity in materials and design); and additional information as requested by the FDA. 21 C.F.R. § 807.87. And, if Bristol-Myers wishes to change substantially the design, components, or manufacturing processes used in making the device, it must submit a new 510(k) Notification. 21 C.F.R. § 807.81(a)(3). The FDA's determination that Bristol-Myers' prosthesis is substantially equivalent to those previously marketed thus binds Bristol-Myers to its representations to the FDA; for all intents and purposes, Bristol-Myers is required to continue to design, manufacture, and label the device as proposed in its original 510(k) Notification. We therefore conclude that 510(k) Notification is a requirement applicable to the device under the MDA. *See Reeves v. AcroMed*

Corp., 44 F.3d 300, 305 (5th Cir.), *cert. denied*, 115 S.Ct. 2251 (1995); *Bokis v. American Medical Sys., Inc.*, 875 F.Supp. 748, 754-55 (W.D.Okla.1995).

IV.

Duvall concedes that if § 360k encompasses common-law claims, and if the MDA imposes requirements on Bristol-Myers' prosthesis, the majority of his claims are preempted.[7] However, Duvall separately argues that his express warranty claim, which is based on Bristol-Myers' brochure for the prosthesis and representations allegedly made by a Bristol-Myers employee, survives preemption under the reasoning of the Supreme Court in *Cipollone*. There is significant disagreement among federal courts as to whether express warranty claims are preempted by § 360k. *Compare King*, 983 F.2d at 1135 (express warranty claim preempted) *with Michael v. Shiley, Inc.*, 46 F.3d 1316, 1325-28 (3d Cir.1995) (express warranty claim not preempted), *petition for cert. filed*, 63 U.S.L.W. 3874 (U.S. June 2, 1995) (No. 94-1971) *and Richman v. W.L. Gore & Assocs., Inc.*, 881 F.Supp. 895, 905 (S.D.N.Y.1995) ("Although some express warranties may be preempted, . . . this Court cannot conclude that all possible express warranties are

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[7] Duvall also asserts that Bristol-Myers has failed to comply with certain reporting requirements imposed under 21 C.F.R. pt. 820. Because of this noncompliance, Duvall argues, Bristol-Myers may not claim preemption. We need not decide whether Bristol-Myers' alleged failure to comply with FDA reporting requirements would prevent it from claiming preemption because Duvall did not present this question to the district court, and there is insufficient evidence of Bristol-Myers' noncompliance to survive summary judgment.

preempted."). We hold that although § 360k preempts express warranty claims to the extent that they are based on FDA-mandated labeling, packaging, and advertising, it does not preempt an express warranty claim that is based on a manufacturer's voluntarily-made representations regarding its product.

Our analysis of this issue is guided by the reasoning of the Supreme Court in *Cipollone* and our decision in *Worm v. American Cyanamid Co.*, 5 F.3d 744 (4th Cir.1993) (*Worm II*). In *Cipollone*, the plaintiff brought an express warranty claim against a cigarette manufacturer based on certain claims made to his deceased mother in its advertisements. *Cipollone*, 112 S.Ct. at 2622. The plurality concluded that the express warranty claim was not preempted because an express warranty is at its core "a contractual commitment voluntarily undertaken." *Id.* at 2622 & n. 23. "A manufacturer's liability for breach of an express warranty derives from, and is measured by, the terms of that warranty. Accordingly, the 'requirements' imposed by an express warranty are not 'imposed under State law,' but rather imposed *by the warrantor.*" *Id.* at 2622.

In *Worm II*, we addressed the question of whether express warranty claims under Maryland law were preempted by a provision of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) that prohibited the imposition by a state of " 'any requirements for labeling or packaging [herbicides] *in addition to or different from* those required under this subchapter.' " *Worm II*, 5 F.3d at 747 (alteration in original) (quoting 7 U.S.C.A. § 136v(b) (West Supp.1995)). Relying on *Cipollone* and noting that Appellants had failed to point to any "statement made by

[Appellee] other than that required and approved by the" Environmental Protection Agency (EPA), we concluded that the express warranty claim was preempted because it was based on labeling mandated by the EPA pursuant to FIFRA. *Id.* at 749.[8]

Based on *Cipollone* and *Worm II*, we hold that Duvall's express warranty claim is preempted to the extent that it is based on FDA-mandated labeling, packaging, or advertising. The MDA requires manufacturers of medical devices to submit proposed labels, advertisements, and package inserts for FDA inspection and regulates the form and appearance of package labels. *See* 21 C.F.R. pt. 801; 21 C.F.R. § 807.87(e). And, a manufacturer is required to resubmit its 510(k) Notification if the device will be "significantly changed or modified." 21 C.F.R. § 807.81(a)(3). A significant change is "[a] change or modification in the device that could significantly affect the safety or effectiveness of the device" or "[a] major change or modification in the intended use of the device." 21 C.F.R. § 807.81(a)(3)(i), (ii). Since many, if not all, such changes will be reflected in the labeling, packaging, and advertising of the device, it is not unreasonable to conclude that – as in *Worm II* – the statements made by Bristol-Myers in the labeling and packaging of its device effectively were mandated by the FDA because they

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[8] We disagree with the Third Circuit that the reasoning of *Worm II* does not apply to a determination of whether an express warranty claim is preempted by § 360k simply because *Worm II* involved "a separate statutory scheme." *Michael*, 46 F.3d at 1327. The relevant language of 7 U.S.C.A. § 136v(b) and § 360k is virtually identical; thus, we perceive no sound basis on which to distinguish *Worm II*.

could not be changed significantly without prior notification to the FDA. *See Kemp v. Pfizer, Inc.*, 851 F.Supp. 269, 273 (E.D.Mich.1994) ("[G]iven the extensive control of the FDA, it would not be inaccurate to assert that the warranties and labeling utilized by [the manufacturer] were imposed upon [it] by federal regulators."). Therefore, Duvall's express warranty claim is preempted to the extent that it is based on FDA-mandated labeling, packaging, and advertising of Bristol-Myers' prosthesis because any promises contained therein were not made voluntarily. *See Cipollone*, 112 S.Ct. at 2622; *Worm II*, 5 F.3d at 749.[9]

We also hold, however, that an express warranty claim is not preempted if it is based on promises made by Bristol-Myers separate and apart from FDA-mandated labeling, packaging, or advertising. And, because these express warranty claims are based upon voluntary promises made by the warrantor, not upon duties imposed under state law, they are not requirements imposed under state law. We therefore conclude that the district court erred in determining that Duvall's express warranty

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[9] The FDA, as amicus curiae, maintains that under *Cipollone* the relevant inquiry is not whether a statement made by a manufacturer was voluntary or was mandated by the government, but rather whether the state imposed the duty to make the statement. Although, of course, a requirement is preempted only if it is imposed by state law, *Worm II* expressly relied on the fact that the statements on which the express warranty claims were based were mandated by the EPA, not made voluntarily by the manufacturer. Our decision in *Worm II* thus requires that we determine whether an express warranty claim is preempted by evaluating whether the statement was made voluntarily.

claim is preempted insofar as it is based on Bristol-Myers' voluntarily-made promises.

V.

Section 360k of the MDA provides for preemption whenever a state requirement would impose an obligation on a medical device manufacturer that is different from or in addition to any requirement applicable to the device under the MDA. With the possible exception of the express warranty claim, all of Duvall's state-law claims would impose different or additional requirements under state law and are therefore preempted. Because we conclude that an express warranty claim is not preempted when it is based on a manufacturer's voluntarily-made representations regarding its product, we reverse in part and remand for further proceedings not inconsistent with this opinion.[10]

AFFIRMED IN PART; REVERSED AND REMANDED IN PART.

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[10] Assuming that Duvall's express warranty claim is not preempted in its entirety, Patricia Duvall's claim is not barred to the extent that Maryland law allows a loss of consortium claim to derive from an express warranty claim. We express no opinion on this question since the issue was not addressed by the parties.

UNITED STATES COURT OF APPEALS

FOR THE FOURTH CIRCUIT

FILED
October 17, 1995

No. 94-1520
CA-93-1072-S

Duvall v. Bristol-Myers Squibb

MANDATE

The judgment of this Court dated 9/25/95 takes effect today.

BERT M. MONTAGUE
CLERK

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

EUGENE DUVALL, et ux.	*	
	*	Civil No. S 93-1072
v.	*	
BRISTOL-MYERS SQUIBB COMPANY, et al.	*	

****

MEMORANDUM OPINION

This is a case removed on diversity grounds from the Circuit Court for Carroll County, Maryland, in which the plaintiffs sought recovery on a number of product liability grounds from the defendants on account of the failure of a penile implant installed in Mr. Duvall's body to work as it should, which allegedly led to physical and emotional injuries. The Court, after deciding the case of *Griffin v. Medtronic, Inc.*, 840 F.Supp. 396 (D.Md. 1994), asked the parties in the present case to brief the question of whether the Medical Devices Amendments of 1990 (MDA) pre-empt plaintiffs' claims. The parties have briefed the issues, and no oral hearing is needed, in light of the recent case law in the area. Local Rule 105.6, D.Md.

There is no disputed question of fact material to the resolution of the questions of law presented by the defendants' summary judgment motion. Thus, if they are clearly entitled to judgment in their favor on the legal issues, they will prevail under Fed. R. Civ. P. 56(c).

The Court, in light of its own decision in *Griffin, supra*, as well as the decisions cited therein and thereafter,

e.g., Mendes v. Medtronic, Inc., ___ F.3d ___ (1st Cir. March 9, 1994), is firmly of the opinion that the MDA pre-empts all state-law based claims asserted by the plaintiffs in this case, which involves a Class III device under the MDA. The claim for breach of express warranty is no different for this purpose, than the claims of breach of implied warranty and strict liability claims that have been held pre-empted in virtually all the cases considering the question. In this case, unlike the barebones health warnings at issue in *Cipollone v. Liggett Group*, 112 S.Ct. 2608, 2621-22 (1992), the breadth and reach of the MDA's labelling and packaging requirements are such that express warranty claims are clearly within the universe of claims pre-empted by the MDA, as the First Circuit noted in *King v. Collagen Corp.*, 983 F.2d 1130, 1135 (1st Cir. 1993).

Finally, the Court has considered the plaintiffs' contention that, because the device in question was marketed as a "substantially equivalent" device (to one already on the market) under the so-called "rule 510(k) process," there can be no pre-emption under the MDA. As to all claims, perhaps, other than defective design, this contention was authoritatively answered by the First Circuit in *Mendes*, and no further discussion of the points there made is needed here. As to the defective design claim, one not reached in *Mendes*, this Court is of the opinion that, although the rule 510(k) process, governed by the detailed provisions of the MDA itself, *viz.*, 21 U.S.C. §360c(i)(A), is not so complex as the pre-marketing approval (PMA) process for newly contrived devices, the rule 510(k) process is nonetheless both rigorous and designed completely to control the marketer's market behavior with regard to the device, which is, after all, the

foundation for the pre-emption analysis in the first place. Certainly, at least in this case, there was a requirement that the 510(k) request be supported with clinical test data subject to agency scrutiny before marketing approval was bestowed. The fact, asserted in an affidavit submitted by the plaintiff, that the approving agency might have had quite a workload is, of course, not material. The Court has no warrant to assume that a heavy workload prevents a federal agency from doing its job properly according to statute.

The other points raised in the briefing do not warrant discussion, and, accordingly, a separate order will be entered, granting the defendants' motion for summary judgment.

Dated: March 30, 1994

/s/ _____
Frederic N. Smalkin
U.S. District Judge

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

EUGENE DUVALL, et ux.	*	
	*	Civil No. S 93-1072
v.	*	
	*	
BRISTOL-MYERS SQUIBB	*	
COMPANY, et al.	*	
	*	

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JUDGMENT ORDER

For the reasons stated in a Memorandum Opinion entered this date, it is, by the Court, this 30th day of March, 1994, ORDERED and ADJUDGED:

1. That the defendants' motion for summary judgment BE, and it hereby IS, GRANTED;

2. That judgment BE, and it hereby IS, ENTERED in favor of defendant, against the plaintiffs, with costs; and

3. That the Clerk mail copies hereof to counsel.

/s/ _____
Frederic N. Smalkin
U.S. District Judge

UNITED STATES DISTRICT COURT
DISTRICT OF MARYLAND

CHAMBERS OF
FREDERIC N. SMALKIN
UNITED STATES
DISTRICT JUDGE

101 W.
LOMBARD STREET
BALTIMORE, MARYLAND
21201
(410) 962-3840
FTS 922-3840

January 14, 1994

LETTER TO COUNSEL

Re: Eugene Duvall, et ux. v. Bristol-Myers Squibb Co., Inc., *et al.*, *Civil No. S 93-1072*

Dear Counsel:

I enclose for your reference a copy of a published opinion I just entered in a case involving heat pacemakers, which are Class III medical devices, regulated under the Medical Devices Amendments (MDA). *Griffin v. Medtronic, Inc.*, ___ F. Supp. ___ (D.Md. 1994). As you can see, I held in that case, following the First and Fifth Circuits, that state-law based product liability claims involving such devices are pre-empted by the MDA.

I do not know if the penile implant at issue in this case is a Class III (or other class) medical device. If it is, it seems to me that the pre-emption issue should be addressed forthwith.

Therefore, and assuming there is no dispute as to whether the implant is such a device, I should like the parties to brief the issue. Defendant's briefing, in the form of a motion for summary judgment, is due 21 days

from the date hereof. Thereafter, the usual briefing times as per Local Rule 105 will govern.

If the implant is not, in fact, a medical device under the MDA, please so notify me at once.

This letter, although informal in format, is nonetheless an Order of Court.

Very truly yours,

/s/ _____
Frederic N. Smalkin
U.S. District Judge

FNS/fns
cc: Court File
Counsel

UNITED STATES DISTRICT COURT

DISTRICT OF MARYLAND

CHAMBERS OF
FREDERIC N. SMALKIN
UNITED STATES
DISTRICT JUDGE

101 W.
LOMBARD STREET
BALTIMORE, MARYLAND
21201
(410) 962-3840

September 28, 1995

David B. Shapiro, Esq.
1101 St. Paul Street
Suite 407
Baltimore, MD 21202

Robert T. Shaffer, III, Esq.
William J. Murphy, Esq.
100 Light Street
Suite 750
Baltimore, MD 21202

Re: *Duvall v. Bristol-Myers, et al. Civil No. S 93-1072*

Dear Counsel:

I trust that, by now, you have had the opportunity to read the opinion of the Fourth Circuit in the captioned case. It strikes me that the next logical step is for me to entertain a motion for summary judgment that goes to the only possible claim that can still be maintained in this case, *viz.*, "an express warranty . . . based on promises by Bristol-Myers separate and apart from FDA-mandated labeling, packaging, or advertising." Slip op. at 13-14. Of course, no one focused precisely on the extent or nature of these claims at the time otherwise dispositive issues in this case were decided.

Thus, in order to flesh out whether there are any such viable claims, defendants will be given 30 days from the date of the notification by letter from me that the mandate has been received in order to submit their second motion for summary judgment, and the plaintiffs will be given a like period within which to oppose it. Defendants will then by [sic] given a 10 day reply period. Do not expect oral argument. Local Rule 105.6, D. Md.

Once again, the period for submission of the renewed motion will only begin after I notify you that the mandate has been received. Until then, you need do nothing.

Very truly yours,

/s/ Frederic N. Smalkin
Frederic N. Smalkin
United States
District Judge

FNS/skp
cc Addressees
Court File – Original

UNITED STATES DISTRICT COURT
DISTRICT OF MARYLAND

CHAMBERS OF
FREDERIC N. SMALKIN
UNITED STATES
DISTRICT JUDGE

101 W.
LOMBARD STREET
BALTIMORE, MARYLAND
21201
(410) 962-3840

October 23, 1995

David B. Shapiro, Esq.
1101 St. Paul Street
Suite 407
Baltimore, MD 21202

Robert T. Shaffer, III, Esq.
William J. Murphy, Esq.
Suite 750
100 Light Street
Baltimore, MD 21202

Re: *Duvall v. Bristol-Myers, et al. Civil No. S 93-1072*

Dear Counsel:

I am writing pursuant to my letter to you of September 28, 1995, to notify you that the mandate of the Fourth Circuit has now been received and docketed in this Court. Therefore, pursuant to my letter of September 28, defendants are given 30 days from the date of this letter in order to submit their second motion for summary judgment, going solely to the surviving express warranty claim(s). Plaintiffs will be given 30 days from the date of submission of defendants' motion in order to oppose the same. Defendants will then be given a 10 day reply period, and I remind you that oral argument will likely not be held.

Although this letter is informal in nature, it nonetheless constitutes an order of court, and the same will be docketed and filed as such in the court file.

Very truly yours,

/s/ _____
Frederic N. Smalkin
United States
District Judge

FNS/skp
cc Addressees
Court File - Original

[LOGO]
DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
8787 Georgia Avenue
Silver Spring MD 20910
JAN 8 1988

Ms. Betty A. Lock
Director, Regulatory Affairs
Surgitek
3037 Mt. Pleasant Street
Racine, Wisconsin 53404

Re: K873558
Surgitak Generation III*
Inflatable Penile Implant
Dated: August 31, 1987
Received: September 2, 1987
Regulatory Class: III

Dear Ms. Lock:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments. You may, therefore, market the device, subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act). The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Performance Standards) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the *Federal Register.* Please note: this response to your premarket notification submission does not affect any obligation you might have under the Radiation Control for Health and Safety Act of 1968, or other Federal Laws or Regulations.

This letter immediately will allow you to begin marketing your device as described. An FDA finding of substantial equivalence of your device to a pre-amendments device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA *approves* your device. Therefore, you may not promote or in anyway represent your device or its labeling as being *approved* by FDA. If you desire specific advice on the labeling for your device please contact the Division of Compliance Operations, Regulatory Guidance Branch (HFZ-323) at (301) 427-8040. Other general information on your responsibilities under the Act may be

obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

/s/ Halyna P. Breslawec
Halyna P. Breslawec, Ph.D.
Director
Division of Gastroenterology-
Urology and General
Use Devices (HFZ-420)
Office of Device Evaluation
Center for Devices and
Radiological Health